

## **REMARKS**

### **I. Claim Status**

Claim 20 has been canceled.

After entry of this Amendment, claims 1-19 will be pending in the application. Of these claims, claims 1-11 and 16 are withdrawn from consideration.

### **II. The Claims Are Patentable Under 35 U.S.C. § 102(b)**

Claim 18 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Hara et al. (U.S. Patent 6,821,107).

Specifically, the Examiner contends that Hara et al. teach fibroblast cells cultured on a carrier comprising an alginate gel layer coated with collagen. The Examiner contends that the presence in the present claims of the chitosan layer between the collagen and alginate gel layers, although perhaps beneficial, does not patentably distinguish the cultured product from Hara et al.

Applicants traverse this rejection, for at least the following reasons.

While the patentability of a product-by-process claim (such as claim 18) is based upon the product itself (as the Examiner notes at page 3 of the Office Action), the Examiner is not free to disregard clear structural distinctions between the product of the art and the claimed product. See MPEP § 2111.

In the present case, the Examiner acknowledges a clear structural distinction between product-by-process claim 18 and the carrier of Hara et al., namely, the chitosan layer. Thus, the

rejection on its face is a legally improper § 102(b) rejection, because the Examiner acknowledges that the product of claim 18 is necessarily distinct from that of Hara et al.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

### **III. The Claims Are Patentable Under 35 U.S.C. § 103(a)**

Claims 12-15 and 17-19 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Hara et al., in view of Huguet et al., Process Biochemistry (1996), and Clapper et al. (U.S. Patent 5,512,474).

Specifically, the Examiner contends that Hara et al. teach a carrier for cell culture comprising an alginate gel layer formed on a porous membrane, and having an extracellular matrix component layer (collagen).

The Examiner admits that Hara et al. do not teach a carrier for cell culture where the collagen layer is bound to a surface of the water-containing gel by means of chitosan as an intermediate layer.

However, the Examiner contends that Huguet et al. teach a microcapsule suitable for microencapsulation of biological materials including cells, which comprises calcium alginate beads that are coated with chitosan as an outermost layer in order to study the rate of release of biological materials such as proteins and dextran from the encapsulated beads.

In addition, the Examiner contends that Clapper et al. teach a cell culture system comprising a support material for anchorage-dependent cell culture, which comprises a stable

combination of a positively-charged molecule, such as chitosan, and a cell adhesion factor, such as collagen.

The Examiner concludes that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the carrier for cell culture of Hara et al. such that the collagen gel layer is bound to a surface of alginate by means of a polycationic polysaccharide such as chitosan, as suggested by Huguet et al. and Clapper et al.

Applicants traverse this rejection for at least the following reasons.

The carrier of the present invention comprises a chitosan layer between the alginate and collagen layers; the chitosan layer is used, in the form of a sheet, to reinforce the carrier. In contrast to the present invention, Hara et al. uses a collagen layer to structurally reinforce the alginate layer. Applicants submit that adding a chitosan layer to the carrier of Hara et al. would not be obvious, because Hara et al. does not suggest that further support or enhancement of cell attachment would be needed, or would be otherwise beneficial, when using a collagen-coated alginate-gel carrier.

Furthermore, Huguet teaches a microcapsule containing chitosan as a core substance. However, because the laminated cell sheet of the present invention is totally different from the microcapsule taught in Huguet, this reference does not teach or suggest that chitosan can be used in the form of a sheet or layer to reinforce a water-containing gel layer.

Moreover, the chitosin layer in the presently claimed carrier confers many unexpected advantages, such as transparency to facilitate observation of culture cells, and permeability of culture medium ingredients, none of which are taught or suggested by the cited references.

Amendment under 37 C.F.R. § 1.111  
USSN 10/612,955

Therefore, Applicants respectfully request reconsideration and withdrawal of this rejection.

#### **IV. Request for Rejoinder**

Pursuant to MPEP § 821.04, Applicants respectfully request the rejoinder of method claim 16 upon the allowance of claim 12.

#### **V. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Amendment under 37 C.F.R. § 1.111  
USSN 10/612,955

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.


Respectfully submitted,

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